

K 961472

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. The submitter of this premarket notification is:

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2. The name of the device is Roeko Dental Dam Silicone. Its common name is dental dam and the classification name is Rubber dam and accessories.
3. The Roeko Silicone Dental Dam is substantially equivalent to the Hygienic brand latex dam.
4. The Roeko dam is a silicone product used in dental procedures. The device consists of a 150 mm x 150 mm green opaque film of less than 1mm in thickness. The device is available with frame, clamp and other accessories for use in dental procedures.
5. The Roeko silicone dam is intended for use as a physical barrier around a tooth to allow isolation from fluids in the mouth during dental procedures. The tooth is isolated by insertion through a hole punched in the center of the silicone sheet. The dental dam is inserted into the oral cavity using frame and clamp accessories. These indications are the same as those claimed for the predicate device.
6. The technological characteristics in terms of physical properties, particularly elongation, are comparable to latex; however, the aging process is very slow, if at all. Chemically, the Roeko dental dam is composed of polymerized silicone rather than latex and contains a catalyst and coloring agent. Biocompatibility tests indicate that Roeko Dental Dam Silicone does not show significantly adverse biological responses. Patients with a latex allergy can now be treated with a silicone dental dam and dentists allergic to latex are able to treat patients with a silicone dental dam. In view of the above, the device is as safe, as effective and performs as well or better than the predicate device.